

Applicant: Patrice Flaherty  
Application No: 10/630,402  
Filing Date: 07/30/2003  
Attorney Docket No: 1066

### REMARKS

Claims 1-32 are pending herein.

Claims 12-23 are withdrawn from consideration.

Claims 1-11 and 24-32 are rejected.

Claim 8 has been canceled.

Claims 1, 7, 9, 10, 24, 31 and 32 are currently amended.

### Claim Rejections under 35 U.S.C. 103

Claims 1-11 and 24-32 were rejected under 35 U.S.C. 103(a) as being unpatentable over Propp (US 5,919,146) in view of Prager (US 4,257,416).

It will be noted that claim 8 has been canceled.

It is respectfully submitted that Propp in view of Prager fails to render remaining claims 1-7, 9-11 and 24-32 obvious under 35 U.S.C. 103(a), as set forth herein below.

#### *Propp in view of Prager fails to teach invention of claims 1-6*

It is respectfully submitted that Propp in view of Prager fails to teach or suggest a device comprising "a main tubing segment...an indicator unit and an access port disposed in *bidirectional* fluid communication with said main tubing segment in branched relationship to each other..." as set forth in amended claim 1 and defined by claims 2-6 as dependent therefrom.

In contrast, Propp teaches *unidirectional* gravity-induced flow of urine from a main tubing

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segment (40), through tubing (44) and into a metering device (48) and a receptacle (56), respectively, of a urine drainage device (20) (col. 3, lines 21-31). Alternatively, Propp teaches *unidirectional* gravity-induced flow of urine from the main tubing segment (40) and through a tube (33) and into a urine collection vessel (22) of a sampling device (10) (col. 4, lines 41-50).

Prager teaches a device in which fluid can be extracted from or infused into a patient through a needle tube (16) and one of multiple tubes (28, 30, 32). However, Prager would fail to provide any teaching, suggestion or motivation to a person of ordinary skill in the art to use the Propp device for bidirectional fluid movement to and from a patient since the design of the Propp device limits movement of fluids unidirectionally and only under the influence of gravity.

It is further respectfully submitted that Propp in view of Prager fails to teach or suggest a device comprising "a main tubing segment... a clamp operably engaging said main tubing segment and adapted to selectively block and unblock flow of the fluids in both directions through said main tubing segment...", as set forth in amended claim 1 and defined by claims 2-6 as dependent therefrom.

In contrast, Propp discloses an anti-reflux valve (74) which is provided in the main tubing segment (40) of the Propp device and is adapted to "prevent reflux of urine towards the bladder" of a patient in which the main tubing segment (40) is inserted (col. 4, lines 23 and 24 of Propp). The anti-reflux valve (74) facilitates flow of urine toward the sampling device (10) and fluid metering device (48), and therefore, is not adapted to "block and unblock flow of the fluids in both directions through [the] main tubing segment", as set forth in amended claim 1.

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While Prager teaches a clamp (52) which is adapted to block and unblock flow of fluids in both directions through a tube (16), it is respectfully submitted that there would be no teaching, suggestion or motivation to replace the one-way anti-reflux valve (74) of the Propp device with the clamp (52) of the Prager device since only unidirectional, rather than bidirectional, blocking of fluid through the main tubing segment (40) is necessary to prevent backflow of urine through the main tubing segment (40) in operation of the Propp device.

Therefore, it is respectfully submitted that Propp in view of Prager fails to render claims 1-6 obvious under 35 U.S.C. 103(a). Reconsideration and allowance of claims 1-6 is therefore respectfully solicited.

*Propp in view of Prager fails to teach invention of claims 7 and 9-11*

It is respectfully submitted that Propp in view of Prager fails to teach or suggest a device comprising "a main tubing segment...a blood volumeter *having a first end disposed in fluid communication with said main tubing segment* and a *second end...at least one air-permeable and liquid-impermeable membrane disposed in fluid communication with said blood volumeter or at said second end of said blood volumeter...*", as set forth in amended claim 7 and defined by claims 9-11 as dependent therefrom.

In contrast, Propp teaches a device having a main tubing segment (40) and a vessel (48) having a first end (44) disposed in fluid communication with the main tubing segment (40) and a second end (52) connected to a urine receptacle (56). A hydrophobic vent (60) is provided in fluid

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communication with the volumeter at the first end (44), rather than at the second end (52), of the volumeter. Prager fails to teach a hydrophobic vent in the Prager device. Therefore, it is respectfully submitted that Prager would fail to provide any teaching, suggestion or motivation to a person of ordinary skill in the art to rearrange the position of the hydrophobic vent (60) from the first end (44) to the second end (52) of the Propp device.

It is further respectfully submitted that Propp in view of Prager fails to teach or suggest a device comprising "a main tubing segment...a blood volumeter...disposed in fluid communication with said main tubing segment...an access port disposed in fluid communication with said main tubing segment in branched relationship to said blood volumeter...*at least one air-permeable and liquid-impermeable membrane...allowing bidirectional fluid movement between said blood volumeter and said access port*", as set forth in amended claim 7 and defined by claims 9-11 as dependent therefrom.

In contrast, Propp teaches a device having a hydrophobic vent (60) which is provided at the same end of a vessel (48) which is connected to the main tubing segment (40) of the device. The hydrophobic vent (60) allows *unidirectional* flow of air from the vessel (48) through the hydrophobic vent (60) as urine *unidirectionally* flows from a patient; through the main tubing segment (40) and vessel (48), respectively; and into a urine receptacle (56). Likewise, a vent (28) is provided in the urine collection vessel (22) of the urine sampling device (10) to accommodate the *unidirectional* flow of air from the vessel (22) as urine *unidirectionally* enters the vessel (22) from a tube (33). Prager fails to teach that the hydrophobic vent (60) allows any type of flow

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whatsoever between the vessel (48) and the vessel (22).

Prager fails to teach a hydrophobic vent in the Prager device. Therefore, it is respectfully submitted that Prager would fail to provide any teaching, suggestion or motivation to a person of ordinary skill in the art to rearrange the position of the hydrophobic vent (60) such that the hydrophobic vent (60) allows *bidirectional* movement of fluid between the vessel (48) and the urine collection vessel (22).

It is further respectfully submitted that Propp in view of Prager fails to teach or suggest a device comprising a main tubing segment... a clamp operably engaging said main tubing segment and *adapted to selectively block and unblock flow of the fluids in both directions through said main tubing segment...*, as set forth in amended claim 7 and defined by claims 9-11 as dependent therefrom, as was set forth herein above with respect to the rejection of claims 1-6.

Therefore, it is respectfully submitted that Propp in view of Prager fails to render claims 7 and 9-11 obvious under 35 U.S.C. 103(a). Reconsideration and allowance of claims 7 and 9-11 is therefore respectfully solicited.

*Propp in view of Prager fails to teach invention of claims 24-32*

It is respectfully submitted that Propp in view of Prager fails to teach or suggest a device comprising "a main tubing segment...a blood volumeter having a first end disposed in fluid communication with said main tubing segment, a second end, an *air flow pathway extending through said blood volumeter between said first end and said second end* and a *bidirectional liquid*

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*flow pathway coinciding with said air flow pathway between said first end and said second end...at least one air-permeable membrane provided in fluid communication with said blood volumeter at said second end of said blood volumeter...”, as set forth in amended claim 24 and defined by claims 25-32 as dependent therefrom.*

In contrast, Propp teaches a device having an air flow pathway which progresses from the interior of the vessel (48) and through a hydrophobic vent (60) provided in a first end (44), rather than a second end (52), of the vessel (48), along which air flow pathway air exits the vessel (48) as urine enters the vessel (48) from the main tubing segment (40). Propp also teaches that the device has a unidirectional liquid flow pathway which progresses from a patient and through the main tubing segment (40), the interior of the vessel (48) and the second end (52) of the vessel (48), respectively, and into the urine receptacle (56). Therefore, Propp teaches that the air flow pathway and the liquid flow pathway must be separate (not coincide) in order for air to remain in the vessel (48) at the first end (44) thereof for air to continue exiting through the hydrophobic vent (60) and urine to continue flowing into the vessel (48).

It is further respectfully submitted that Propp in view of Prager fails to teach or suggest a device comprising “a main tubing segment...a clamp operably engaging said main tubing segment and *adapted to block and unblock flow of the fluids in both directions* through said main tubing segment...”, as was set forth herein above with respect to the rejection of claims 1-7 and 9-11.

It is further respectfully submitted that Propp in view of Prager fails to teach or suggest a device comprising “a main tubing segment...a blood volumeter...disposed in fluid communication with

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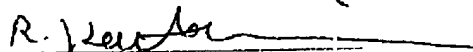
said main tubing segment... an access port disposed in fluid communication with said main tubing segment...at least one air-permeable membrane provided in fluid communication with said blood volumeter...*wherein said at least one air-permeable membrane allows bidirectional fluid movement between and through said blood volumeter and said access port...*", as set forth in amended claim 24 and defined by claims 25-32 as dependent therefrom, as was set forth herein above with respect to the rejection of claims 7 and 9-11.

Therefore, it is respectfully submitted that Propp in view of Prager fails to render claims 24-32 obvious under 35 U.S.C. 103(a). Reconsideration and allowance of claims 24-32 is therefore respectfully solicited.

#### *Conclusion*

Every effort has been made to amend applicant's claims in order to define the invention in the scope to which it is entitled. Accordingly, reconsideration and allowance of claims 1-7, 9-11 and 24-32 is respectfully solicited.

Respectfully submitted.

  
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